

## REMARKS

The amendment to claim 1 has been made in accordance with the examiner's suggested claim language in her office action dated October 25, 2002, paper 14. The amendment to the claim should therefore overcome examiner's rejection under 35 USC 112, second paragraph. Amendment to claims 30 through 32 have been made to make the claim language consistent with other claims in this application. New claims 36, 37, 38 and 39 have been added to better identify the claimed subject matter. Support for new claims 36-39 can be found on page 15, line 6 of the applicants' specification. Therefore, the amendment to the claims, and the addition of new claims 36-39, do not constitute new matter.

(1) The examiner's final rejection of claims 1, 11, 12 and 30 as being anticipated by Mbah, et al., is respectfully traversed.

The examiner maintains that Mbah, et al., anticipate the claims because "Mbah teaches ethanol, acetone and chloroform extracts of the leaves, stems, stem bark, roots and root bark of *Napoleonaea imperialis* which exert antimicrobial activity against bacterial species." The examiner contends that she was not persuaded by the applicants' arguments because Mbah, et al., teach ethanol, acetone and chloroform extracts that exert antibacterial activity. Thus, the examiner alleges that since Mbah, et al., disclose ethanol, acetone and chloroform extracts of leaves, stem, stem bark, root and root bark of *N. imperialis* that exhibit antibacterial activity against the cited bacteria, Mbah, et al., also anticipate the applicants' claimed subject matter even though applicants' disclosure does

not disclose or claim activity against those specific bacteria. Rather, applicants disclose that the obtained extracts were screened “to detect antifungal, antimalarial, antileishmanial and antitrypanosomal activities, etc.” (see page 11, lines 7-8 of the applicants specification), something that Mbah, et al., do not disclose or imply. The examiner is reminded that anticipation under 35 USC 102(b) states that “the invention was...described in a printed publication...” This has been interpreted to mean that a reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” See MPEP 706.02. Since Mbah, et al., fails to meet the standards of prior art under 35 USC 102(b), it is the applicants’ position that Mbah, et al., cannot anticipate the applicants’ application and claimed subject matter and that the examiner has interpreted Mbah, et al., beyond the scope of the publication.

The examiner’s position is beyond the scope of Mbah, et al., for additional reasons. The applicants’ invention details the desirability of extracts obtained from *N. imperialis* seeds due to the exhibition of antileishmanial activity. See page 14, line 30 through page 16, lines 6 of the applicants’ specification. Mbah, et al., is silent on the seed efficacy and further limited in its scope as stated: “However, the absence of toxic affects for the flavonoids and tripenoids is very important for testing their eventual (emphasis added) activity on human lymphocytes.” Mbah, et al., do not disclose or claim any thing other than the initial testing of “leaves, stem, stem bark, root and root bark” because of their efficacy in traditional African medicine. They cannot anticipate antibacterial activity in the manner disclosed by applicants, if only limited testing was conducted. In fact, the Mbah, et al., reference tests *N. imperialis* in a preliminary study

used to determine the possible efficacy of these plants on *Staphylococcus*, *Bacillus*, and *Pseudonoma* type bacteria. Mbah, et al. does not disclose any and all antibacterial activity and definitely does not disclose antiprotozoal or antifungal activity as disclosed by the applicants of the present invention. Specifically, Mbah, et al., does not disclose the use of *N. imperialis* in the treatment of *Leishmania*. Initial testing of efficacy against one group of bacteria cannot support an inherency argument for other and all types of bacteria, as is suggested by the examiner's rejection, because the chemical and biological reactions between *N. imperialis* and pathogens vary greatly. Therefore, Mbah, et al., cannot anticipate the instant claims.

It has also been brought to the applicants' attention that the Mbah, et al., group publication was a preliminary study to gain funding interest. As such, the testing was limited and did not anticipate, as the examiner contends, its efficacy on the type of antibacterial activity disclosed and claimed by applicants. The applicants' position can further be substantiated by the authors of the cited publication. As such, applicants shall be submitting 132 affidavits from at least one of the authors of the Mbah, et al., reference. This affidavit will show that the examiner's position is beyond the scope of the reference, as Mbah, et al., could not have anticipated antileishmanial activity based on the limited testing conducted and disclosed in the publication, for the reasons discussed above. The affidavits are being obtained by the applicant and shall be made of record as soon as they are received. Due to extreme hardships, these affidavits cannot be authenticated by a U.S. Consular Officer (as applicable to PTO oaths and declarations for non-Hague convention countries) at this time. They are being signed in Dr. Okunji's (applicant) presence, and Dr. Okunji, a U.S. legal alien, will attest to their authenticity in his own

132 affidavit. The extreme hardships are due to the current political situation in Nigeria, as corroborated by the Consular Information Sheet published by the United States Department of State, Bureau of Consular Affairs (attachment A), and travel conditions in the interior portions of Nigeria. The examiner is respectfully requested to consider these affidavits prior to rendering an office action as they bear direct merit on the examination of this application.

(2) The examiner's final rejection of 1, 11, 12, 30 and 31, as necessitated by amendment, as being anticipated by Kapundu, et al., is respectfully traversed.

The examiner cites Kapundu, et al., because it "teaches a methanolic extract obtained from the seeds of *Napoleonaea imperialis*. The reference anticipates the claimed subject matter." The applicants' respectfully disagree with the examiner's position.

Kapundu, et al., identify a prosapogenin structure obtained after the seed saponin of *N. imperialis* is hydrolyzed. The methanolic extract is a first step in a two-step process for identifying the structure. In contrast, the applicants disclose and claim a methanol extract of powdered *N. imperialis* seed for testing efficacy against Leishmania and other pathogens. The methanol seed fraction shows direct inhibitory effects against the growth of Leishmania promastigotes. See page 15, lines 5+ of applicants' specification. The extract claimed is obtained without hydrolysis. In order for Kapundu, et al., to anticipate the applicants' invention, applicants would have to have disclosed or claimed a hydrolyzed organic extract of *N. imperialis*. Applicants do not do so, as further hydrolysis would reduce the efficacy of the *N. imperialis* extract against Leishmania and

other antibacterial activity, thus rendering applicants' invention inoperable. Alternatively, Kapundu, et al., must disclose or imply the use of the methanolic seed extract for antibacterial activity. Kapundu, et al., make or implies no such disclosure. Since neither of these criteria is met, Kapundu, et al., cannot anticipate the applicants' claimed invention. Note also that the applicants of the present invention are aware of the contributions of the Kapundu, et al., reference, as it was cited in Dr. Okunji's doctoral thesis as a preliminary finding to the use of African plants in traditional medicine. Dr. Okunji shall be providing a statement regarding this reference in his 132 affidavit.

(3) Claims 1, 11, 12 and 30-32 were finally rejected as being anticipated by Ekpendu, et al., as necessitated by amendment.

The examiner contends that Ekpendu, et al., teach hexane, ethyl acetate and methanol extracts of the root bark of *N. imperialis*, thereby anticipating applicants' claimed invention. The examiner's contention is respectfully traversed.

Ekpendu, et al., disclose hydrolyzed hexane, ethyl acetate and methanolic compounds (see Ekpendu, et al., page 76) starting with the crude extract from the root bark of *N. imperialis*. Similar to Kapundu, et al., discussed above, this step is necessary for Ekpendu, et al., for compound identification as Ekpendu, et al., is not directed to testing *N. imperialis* for its efficacy against bacteria. The introduction to Ekpendu, et al., discusses the use of *N. imperilis* (sic) in herbal preparations through traditional African medicines for its known use against a host of diseases. Were Ekpendu, et al., to anticipate applicants claimed invention, it would have to disclose or imply that hydrolysis of the crude extracts were unnecessary, in addition to its efficacy as a biological extract

for treating bacterial pathogens. Ekpendu, et al., fail to disclose or imply such. Alternatively, hydrolysis is unnecessary to the applicants' invention, and in fact would render applicants' invention inoperative, as the efficacy of the *N. imperialis* extract would be compromised. Therefore, Ekpendu, et al., cannot anticipate applicants' claimed invention.

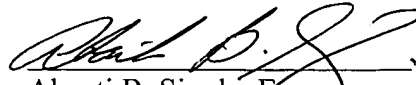
These and other facts distinguishing Ekpendu, et al., from the applicants' invention shall be attested to by at least one of the authors of the Ekpendu, et al., group through a 132 affidavit. As discussed above, Dr. Okunji is obtaining the 132 affidavits from the authors who are located in Nigeria. Dr. Okunji will be following the same protocol in obtaining these affidavits as with those of the Mbah, et al., group. The examiner is respectfully requested to consider these affidavits prior to rendering an office action.

For the reasons given above, it is the applicants' position that the existing claims, amended claims and newly added claims overcome the examiner's rejections. Early allowance of the claims is respectfully solicited.

Please send all correspondences to: Elizabeth Arwine, Esq.: Office of the Staff Judge Advocate; U.S. Army Medical Research & Materiel Command; 504 Scott Street, Fort Detrick, MD 21702-5012; Attn: MCMR-JA (Ms. Arwine).

Please direct any questions regarding this case to Abanti B. Singla, Esq., at (410) 964-9553.

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